510(k) SUMMARY

Lanx LLC's Posterior Cervicothoracic Spinal Fixation System

Name of Firm / Contact

Lanx, LLC
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021
303-443-7500
Contact Person: Greg Causey
Date Prepared: July 9, 2007

DEC 2 8 2007

Name of Device

LANX Posterior Cervicothoracic Spinal Fixation System

Common or Usual Name

Spinal Fixation Appliance

Product Code / Classification Name

KWP - 21 CFR 888.3050 - Spinal Interlaminal Fixation Orthosis

Regulatory Class

Class II

Predicate Devices

K052317, K032394	OASYS™ System	Stryker Spine
K052180, K003780	VERTEX™ Reconstruction System	Medtronic Sofamor Danek USA, Inc.
K042508	Mountaineer OCT Spinal System	Depuy Spine, Inc.
K033961, K043229	Altius M-INI OCT System	Interpore Cross (now Biomet Spine)
K023675	Axon	Synthes Spine
K030197	Ascent	Blackstone
K052201	Solanas	Alphatec Spine

Intended Use / Indications for Use

When intended to promote fusion of the cervical spine and the thoracic spine (C1-T3) in skeletally mature patients, the LANX Posterior Cervicothoracic Spinal Fixation System (PCFS) is indicated for the following:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Failed previous fusion
- Tumor

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Device Description

The Lanx Posterior Cervicothoracic Spinal Fixation System consists of various titanium alloy screws, rods, hooks, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

Performance Data

Performance testing was performed per ASTM F1717 and F1798 to characterize the LANX Posterior Cervicothoracic Spinal Fixation system .

Substantial Equivalence

Equivalency of this device is based on similarities in intended use, materials, and design to other currently marketed Posterior Cervicothoracic Spinal fixation systems. Mechanical testing demonstrated comparable mechanical properties to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2007

Lanz, LLC
% Mr. Greg Causey, Ph.D.
Director, Fusion Technologies
390 Interlocken Crescent, Suite 890
Broomfield, CO 80021

Re: K071905
Trade/Device Name: LANX Postierior Cervicothoracic Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 7, 2007
Received: November 8, 2007

Dear Dr. Causey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 1

Indications for Use Statement

510(k) Number (if known): K071905

Device Name: LANX Posterior Cervicothoracic Spinal Fixation System

Indications for Use:

When intended to promote fusion of the cervical spine and the thoracic spine (C1-T3) in skeletally mature patients, the LANX Posterior Cervicothoracic Spinal Fixation System (PCFS) is indicated for the following:

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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)
Division of General Restorative, and Neurological Devices

510(k) Number K071905